



NDA 21-073/S-021

Takeda Pharmaceuticals North America, Inc.
Attention: Janet Haskins
Manager, Regulatory Affairs
475 Half Day Road, Suite 500
Lincolnshire, IL 60069

Dear Ms. Haskins:

Please refer to your supplemental new drug application dated April 7, 2003, received April 8, 2003, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Actos® (pioglitazone HCl) Tablets, 15 mg, 30 mg, and 45 mg.

We acknowledge receipt of your submission dated May 30, 2003, containing final printed labeling.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to **CLINICAL PHARMACOLOGY** section, **Metabolism** subsection, and **Drug-Drug Interactions** subsection, **PRECAUTIONS** section, **Drug Interactions** subsection, and **Carcinogenesis, Mutagenesis, Impairment of Fertility** subsection, of the package insert. The labeling also reflects changes to the package insert as agreed in our approval letter dated January 17, 2003, to supplement 017.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the labeling.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: package insert (FPL submitted on May 30, 2003)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Orloff

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